UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FWK Holdings, L.L.C., on behalf of itself and all others similarly situated,

Plaintiff,

vs.

TELIGENT, INC., PERRIGO COMPANY PLC, TARO PHARMACEUTICAL INDUSTRIES LTD., and TARO PHARMACEUTICALS USA, INC.

Defendants.

No.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. The plaintiff FWK Holdings, L.L.C., on behalf of itself and all others similarly situated (collectively "Plaintiffs"), bring this Class Action Complaint on behalf of a Class (defined below) of direct purchasers who purchased generic econazole nitrate products ("econazole") directly from defendants Teligent, Inc., Perrigo Company PLC, Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals USA, Inc.

2. The defendants and co-conspirators engaged in an overarching anticompetitive scheme in the market for generic econazole to artificially inflate prices through unlawful agreements between and among would-be competitors. The plaintiff seeks damages incurred due to defendants' and co-conspirators' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

3. The direct, foreseeable, and intended consequence of the defendants' anticompetitive scheme was to cause the plaintiff and Class Members to pay more for generic econazole than they otherwise would have paid in the absence of the defendants' unlawful conduct. As set forth below, the defendants' scheme violates Section 1 of the Sherman Act, 15 U.S.C. § 1 ("Sherman Act").

4. The plaintiff makes the allegations herein based on personal knowledge of these matters relating to itself and upon information and belief as to all other matters.

II. NATURE OF THE CASE

5. For years, the defendants colluded to restrain and/or eliminate competition by engaging in a conspiracy to foreclose competition in the United States market for generic econazole, a topical antifungal, in violation of Section 1 of the Sherman Act. Through this anticompetitive conduct, defendants have imposed unlawful overcharges on generic econazole purchasers.

6. The plaintiffs seek redress for the overcharge damages resulting from defendants' unlawful conspiracy and other anticompetitive conduct in violation of Section 1 of the Sherman Act. Were it not for the defendants' illegal conduct, the plaintiff and Class Members would not have paid supracompetitive prices for generic econazole.

7. The plaintiff's allegations are based in part on information made public during government investigations of the defendants for alleged unlawful conduct in the generic drug industry. In 2014, the U.S. Department of Justice, Antitrust Division ("DOJ") began investigating alleged criminal conduct in the generic drug industry, leading to the issuance of a grand jury subpoena from the DOJ to the defendant Taro Pharmaceuticals USA, Inc. on September 8, 2016. Public filings disclose that the DOJ is investigating Taro's generic drug pricing, and generic econazole is not the only drug at issue.

8. The DOJ's 2014 investigation followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the U.S. Senate Health Education Labor and Pensions ("HELP") Committee and the U.S. House Energy and Commerce Committee requesting hearings on the significant spike in generic drug pricing.[1] The NCPA's news release reports price hikes on essential generic drugs exceeding 1,000% in some instances, according to its survey of over a thousand community pharmacists.

[1] News release available at http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say.

III. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 4 of the Clayton Act, 15 U.S.C. § 15. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

10. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(b) and (c), because during the Class Period the defendants transacted business throughout the United States, including in this District.

11. During the Class Period, the defendants sold and distributed generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of generic econazole in the United States, including in this District. The defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

12. This Court has personal jurisdiction over each defendant because, inter alia, each defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of generic econazole throughout the United States, including in this District; (c) had and maintained substantial contacts within the United States, including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate the prices for generic econazole that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. PARTIES

A. Plaintiff

13. The plaintiff FWK Holdings, L.L.C. is an Illinois limited liability company located in Glen Ellyn, Illinois. The plaintiff is the assignee of antitrust claims possessed by Frank

W. Kerr Company ("Kerr") and brings this action as successor-in-interest to Kerr's claims arising from its purchase of econazole during the Class Period directly from one or more of the defendants at artificially and unlawfully inflated prices.

B. Defendants

14. The defendant Teligent, Inc. ("Teligent") is a Delaware corporation that has its principal place of business in Buena, New Jersey. Teligent markets and sells generic econazole throughout the United States. Teligent is a specialty generic pharmaceutical company engaged in the development, manufacture, and marketing of generic topical and branded generic injectable pharmaceuticals, and it primarily markets its generic drug products to drug wholesalers, retail drug chains, distributors, and government agencies. Prior to October 2015, Teligent operated under the name IGI Laboratories, Inc. ("IGI Labs"). Teligent has manufacturing facilities in Buena, New Jersey. During the Class Period, Teligent sold generic econazole to purchasers in this District and throughout the United States.

15. The defendant Perrigo Company PLC ("Perrigo") is an international consumer healthcare and pharmaceutical company in Dublin, Ireland, that develops, manufactures, and markets generic and specialty pharmaceutical drugs, including econazole, throughout the United States. Perrigo's U.S. headquarters is in Allegan, Michigan. During the Class Period, Perrigo sold generic econazole to purchasers in this District and throughout the United States.

16. The defendant Taro Pharmaceutical Industries Ltd. ("Taro Ltd.") is an Israeli company with its principal place of business in Haifa Bay, Israel. Taro Ltd. develops, manufactures, and markets prescription drugs, including econazole, throughout the United States. Taro Ltd. has operated in the United States principally through its subsidiary, defendant Taro Pharmaceuticals USA, Inc. ("Taro Inc."). During the Class Period, Taro Ltd. sold generic econazole to purchasers in this District and throughout the United States.

17. The defendant Taro Inc. is a New York corporation with its principal place of business in Hawthorne, New York. Taro Inc. is the wholly-owned subsidiary of Taro Ltd. and is responsible for the marketing and sale of generic econazole throughout the United States. During the Class Period, Taro Inc. sold generic econazole to purchasers in this District and throughout the United States.

18. The defendants have engaged in the conduct alleged in this Complaint, and/or the defendants' officers, agents, employees, or representatives have engaged in the alleged conduct while actively involved in the management of the defendants' business and affairs.

V. UNIDENTIFIED CO-CONSPIRATORS

19. Various other persons, firms, entities and corporations, not named as defendants in this complaint, have participated as co-conspirators with the defendants in the violations alleged herein, and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.

20. The true names and capacities, whether individual, corporate, associate, or representative, is presently unknown to the plaintiff. The plaintiff may amend this complaint to allege the true names and capacities of additional co-conspirators as they are discovered.

21. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with the defendants in their unlawful monopolization as described herein.

22. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

VI. FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

23. Generic drugs provide a lower-cost but bioequivalent alternative to brand name drugs. Before any generic drug can be marketed, FDA requires rigorous testing to ensure it has the same strength, quality, safety, and performance as the brand name. By law, generics must have the exact same amount of active ingredient and must be "therapeutically equivalent" to the brand, meaning they must meet exacting bioequivalence testing specifications so patients can expect "equal effect and no difference when [generics are] substituted for the brand name product." [2]

24. To obtain marketing approval for a generic drug, an Abbreviated New Drug Application ("ANDA") must be filed with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs; "abbreviated" because so long as the ANDA includes data showing bioequivalence to the brand, the ANDA sponsor can reference efficacy data supporting approval of the brand (described in the regulations as the "Reference Listed Drug" or "RLD" for short) instead of repeating all the same clinical trials itself. Upon the FDA's determination that bioequivalence to the brand has been established, the ANDA will be approved and may be marketed in the U.S. as substitutable with the RLD.

25. Although equivalent from a safety and efficacy standpoint, generic versions of brand name drugs are priced significantly below their brand name counterparts, and because of this rapidly gain market share from the brand beginning immediately following launch. Indeed, in every state pharmacists are permitted (and in many states required) to substitute a generic

[2] http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G.

product for a brand name product a note from a doctor that the brand name product must be dispensed as written.

26. It is well established in economic literature that competition by generic products results in lower prices for drug purchasers. In the period before generic entry, a brand name drug commands 100% of the market share for that drug and the brand name manufacturer can set the price free from competitive market forces. But once the first lower-priced generic enters, a brand name drug rapidly loses sales due to automatic pharmacy counter substitution, and generics capture as much as 80% of the market or more within months of launch. And as more generics become available, generic prices only decline further due to competition among generics, and the brand drug's share of the overall market erodes even faster. These cost reductions to drug purchasers were the very legislative purpose behind the abbreviated regulatory pathway for generic approval.[3]

27. Generic competition, under lawful and competitive circumstances, reduces drug costs by driving down the prices of both generic versions of the brand name drug and the brand name drug itself, and every year new generic drugs result in hundreds of billions of dollars in savings to consumers, insurers, and other drug purchasers.

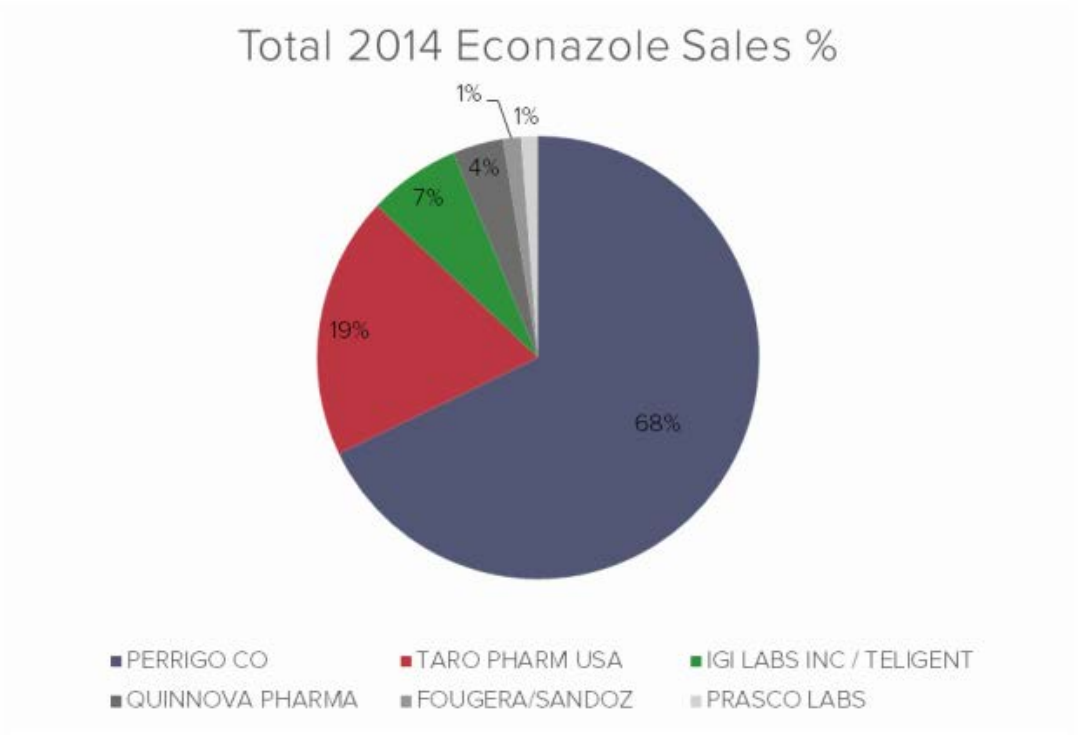
B. Generic Econazole Market and Pricing Information

28. Generic econazole is a prescription topical cream antifungal used to treat a variety inflammatory skin infections (including, *e.g.*, tine, pityriasis veriscolor, tinea pedis, dermatophysis, and eczema marginatum). The market generic econazole is mature, as the product has been on the market since 1999. More than one million patients in the United States were prescribed the drug during the Class Period. In 2015 alone, total sales revenue for

[3] H.R. Rep. No. 98-857, pt. 1, at 1 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2647.

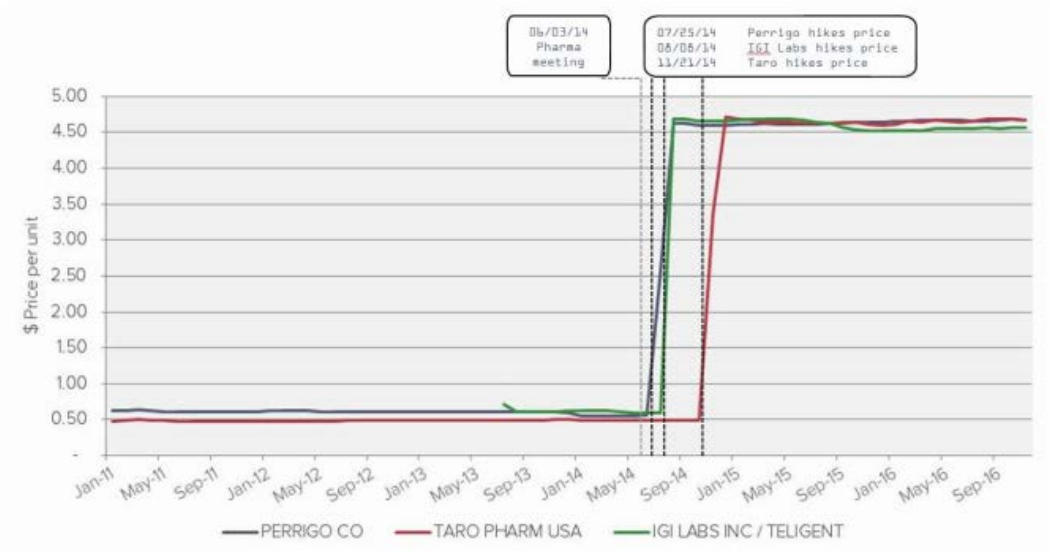
econazole spiked to well over $400 million, which exceeds the sales revenue for the same products from 2011-2014 combined. This type of revenue growth in a mature is evidence of defendants collusion.

29. During the entirety of the class period, the three defendants dominated to econazole market, with their sales making up about 94% of all U.S. econazole sales and 97.3% of the generic econazole market. In 2014 Perrigo's econazole sales exceeded $146.7 million, Taro's exceeded $41.4 million, and Teligent's exceeded $14.49 million:

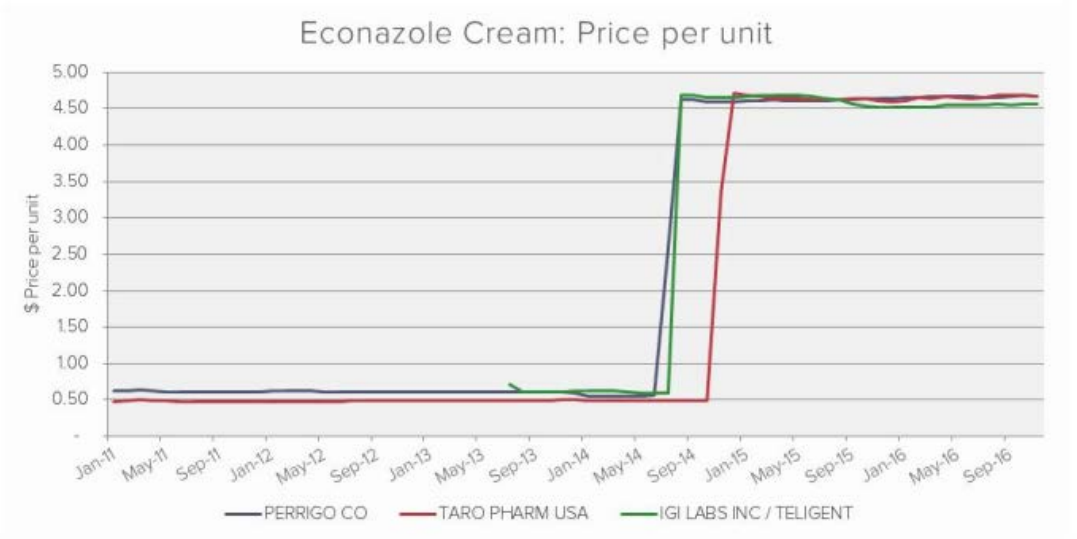


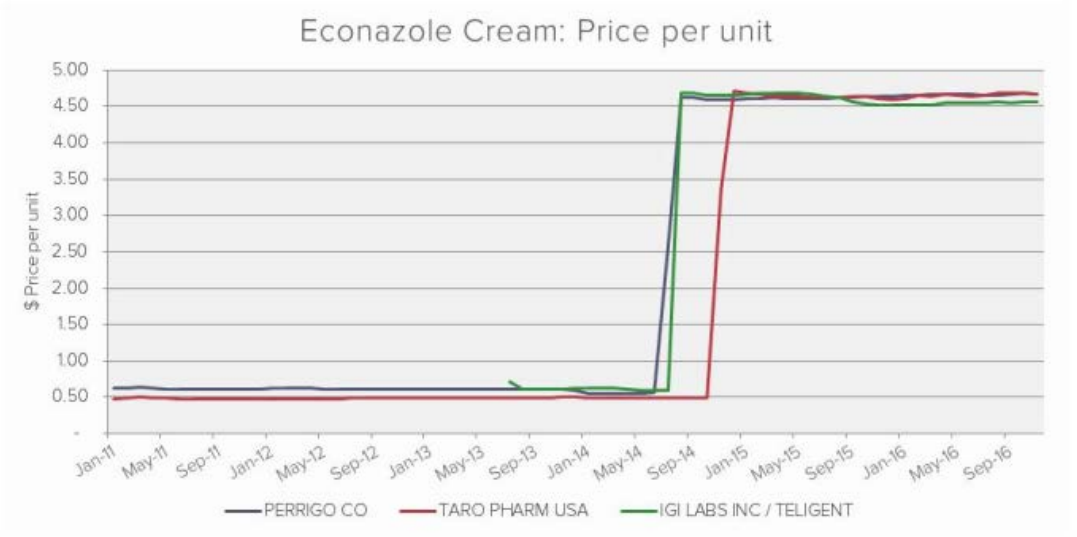
30. Prior to June 2014, the pricing of generic econazole had for years remained stable at $0.79. However, prices inexplicably increased sharply in the four months following June 2014, which is when generic pharmaceutical manufacturers met for a 3-day conference in Bethesda, Maryland.

Defendants' Econazole List Prices



31. In the months following the June 2014 generics meeting, the defendants engaged in a coordinated series of price hikes, jointly raising econazole prices by 539% in the second half of 2014 alone, and collusively maintaining prices at that level thereafter. The defendants' price hikes occurred in lockstep, with all raising prices to virtually identical levels in a four month period:

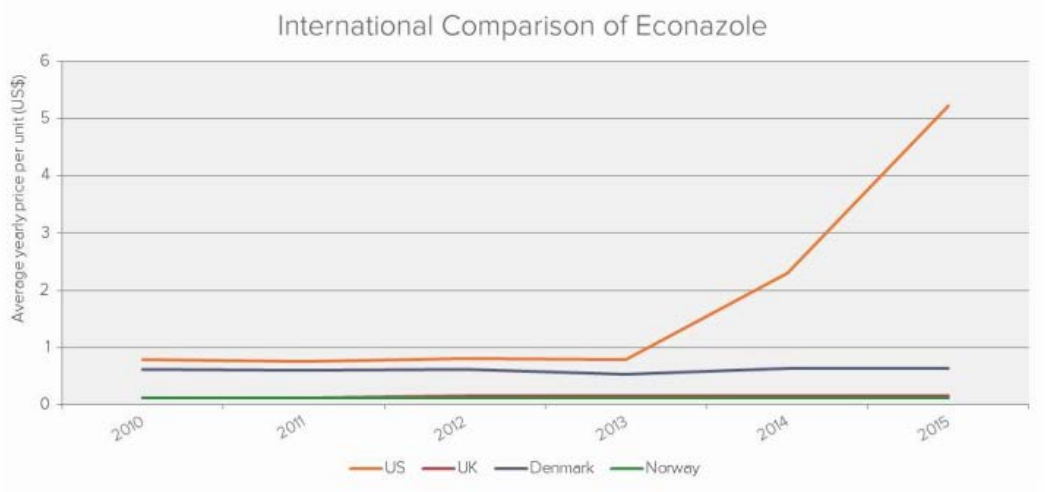




32. There are no potential drug shortages or supply disruptions, or any other lawful market phenomena, to explain the price increases. Federal law requires mandatory drug shortage reporting for drug manufacturers.[4] None of the defendants reported any drug shortages or supply disruptions to the FDA in explanation for the supracompetitive pricing of econazole. And even the defendants themselves cannot muster any meaningful explanation for the coordinated price

[4] Title IX of the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA")

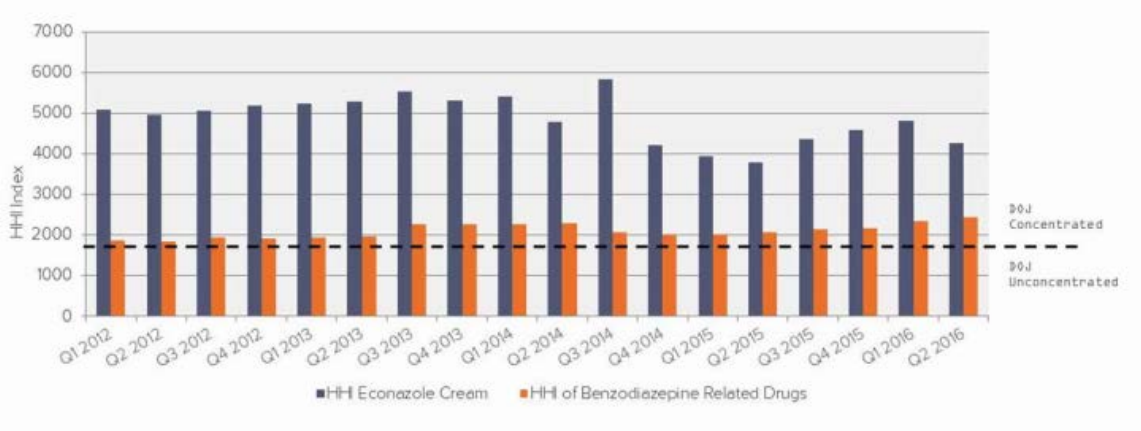
increases. Tellingly, there were no similar price hikes in other countries, including, for example, in the United Kingdom, Denmark, or Norway, where prices have remained flat.



33. Nor does any change in marketplace explains the rising prices—in 2014, the defendants accounted for around 94% of the annual econazole sales and 97.3% of generic econazole sales, and for years the unit prices, the respective market shares of competitors, had remained relatively constant.

34. There have been at least three or more separate manufacturers of generic econazole on the market at all relevant times during the class period. Under accepted economic principles of competition, when there are multiple generics on the market, prices should remain at highly competitive, historic levels, and would not increase as they did here absent

anticompetitive conduct; and that increase is itself suggestive of the defendants' collective market dominance, absent which their pricing excesses would be disciplined by losing market share to non-colluding competitors. The defendants' collective dominance is also apparent when comparing the Herfindahl-Hirschman Index ("HHI") scores for econazole and benzodiazepine (another generic drug). HHI is a standard measure of firm concentration in relation to a given industry and an indicator of the amount of competition in that industry. An HHI score of 0 indicates perfect competition whereas a score of 10,000 indicates a monopoly. The DOJ classifies an industry as "concentrated" if the HHI exceeds 1,800 and "highly concentrated" if it exceeds 2,500.[5] As shown below, since the beginning of 2012, econazole's HHI on average shows a highly concentrated market. In contrast, the benzodiazepine index was only half that of econazole during the same timeframe and its price movements demonstrated relative stability:



C. Defendants' Anticompetitive Activities

35. During the Class Period, the defendants conspired, combined, and contracted to fix, raise, maintain, and stabilize prices at which generic econazole would be sold, which had the intended and actual effect of causing the plaintiff and the other members of the proposed Class to

[5] *See* https://www.justice.gov/atr/herfindahl-hirschman-index.

pay artificially inflated prices above prices that would exist competitive market had determined prices for generic econazole.

1. Annual Reports and Investor Communications

36. The defendants' statements and admissions in their annual reports and other investor communications reveal defendants goal of increasing generic drug prices and maintaining them at supracompetitive levels.

a. Teligent

37. According to Teligent's 2015 Annual Report, econazole accounted for 45% of the company's total revenues in 2015 and 38% in 2014.

38. On July 24, 2014 – just as econazole prices were beginning to rise – Jason Grenfell-Gardner, President and CEO of what was then IGI Laboratories, stated on a second quarter earnings call that. "[P]rices go up and prices down. What we as a management team have to do is to ensure that we remain alert and we try to maximize the value we can."

39. On the next earnings call, October 24, 2014, Grenfell-Gardner noted that maximizing value through price increases helped to significantly increase the company's revenues: "Year-to-date in 2014, we recognized $9.3 million in sales if IGI label products, that's an increase of 123% over the same period last year. This growth has been driven partially . . . from significant price increases for core products in the portfolio."

40. Grenfell-Gardner and Jenniffer Collins, Teligent's CFO, continued to recognize the "favorable pricing environment" for econazole in the April 28, 2015, earnings call for the first quarter of 2015. The company's 56% increase in revenue over the same period in 2014 was attributed by Collins to econazole, noting that the product represented 53% of the company's total revenue for the first quarter of 2015.

b. Perrigo

41. Perrigo stated in its 2015 Annual Report that it intended to "[B]roaden[] leadership in our core base business of extended topical products with *limited competition* and *attractive margins*." (emphasis added).

42. Joseph C. Papa, chairman, CEO, and president of Perrigo, has repeatedly emphasized in his statement in quarterly earnings calls that Perrigo's strategy is to maintain "flat or slightly up" pricing across its portfolio by taking advantage of opportunities to increase prices. On May 7, 2014, in a third quarter earnings call, Papa noted that he "absolutely agree[d] that there are some opportunities for us in different business segments."

43. During the August 14, 2014 fourth quarter earnings call, held within months of the spike in econazole prices, Papa explained Perrigo's strategy further, noting that "there are some opportunities on pricing in the Rx category . . . Our logic being that in any given year, in any given quarter we may raise prices on product A but then we make concession on Product B and C."

44. Papa noted that prescription drugs, such as econazole, provided the "greatest upside" for pricing. He attributed this upside as responsible for "record results, growing sales 12% with an adjusted operating margin of 46%" during the 2015 first quarter earnings call on February 7, 2015.

c. Taro

45. During a November 10, 2014, earnings call, Taro CEO Kal Sundarum attributed the company's significant growth to price increases:

> In 2010, as per IMS data, Taro was ranked third among the genetic dermatology companies in USA. In terms of sales, now it is ranked number one for the past three years. U.S. remains the dominant market for Taro. Taro's earnings per share also has grown 50% CAGR, compounded annual growth, since 2010. Taro's sales and

> earnings growth is attributable to upward price adjustments and the prudent life cycle management of our product portfolio while our overall volumes remain relatively constant and we remain cautious about the long-term sustainability of these prices. Our sales and earnings growth is attributable to upward price adjustments and prudent life cycle management of our portfolio, while our overall volumes remain relatively constant. Again market to volume fluctuations can happen for very different reasons as and when a new generation product comes, it will have impact on the older generation product. And once again I am saying generics remain to be sort of, what do you say cost value for money and competitive. I don't think there will be any significant -- we have seen any significant impact of volume shifting because of price adjustments.

46. Sundarum again emphasized Taro's strategy of relying upon high-priced generics in a November 4, 2015, earnings call, stating that "We are a specialty generic company, so by definition, our portfolio will be obviously narrow but sort of focused. We operate in niche markets; smaller volumes, but better priced."

2. Defendants' Collusion Opportunities through Trade Organizations.

47. The defendants have ample opportunities to communicate through trade organizations, and have availed themselves of those opportunities to collude.

48. The industry intelligence-gathering reporting firm *Policy and Regulatory Report* ("PaRR") has reportedly obtained information regarding the investigation of generic drug companies by the DOJ, and has indicated that the DOJ is investigating the extent to which trade organizations have been used as forums for collusion between sales personnel among competing generic drug companies.[6]

[6] http://www.fiercepharma.com/story/actavis-gets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07.

49. For example, the Generic Pharmaceutical Association ("GPhA") is the "leading trade association for generic drug manufacturers."[7] GPhA was formed in 2000 from the merger of three industry trade associations: the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

50. The defendant Perrigo has a representative on GPhA's 2016 Board of Directors.

51. GPhA's website touts, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry" and lists its "valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections."[8] GPhA's "member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year."

52. The defendants each had representatives at the GphA meetings in Maryland on June 3-4, 2014, and November 2-4, 2014.

3. Industry Commentary

53. Comments from industry analysts suggest manufacturers' alternative explanations for the price hikes (e.g., supply disruptions) are mere pretextual, intended to shroud the defendants conspiratorial conduct and ends. For instance, Richard Evans at Sector & Sovereign Research recently wrote: "[a] plausible explanation [for price increases] is that generic manufacturers, having fallen to near historic low levels of financial performance are cooperating

[7] http://www.gphaonline.org/about/the-gpha-association.

[8] http://www.gphaonline.org/about/membership.

to raise the prices of products whose characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation."[9]

54. A *Bloomberg* reporter, Alan Katz, wrote on December 12, 2013 that:

> Bill Drilling, an owner of a pharmacy in Sioux City, Iowa, apologizes as he rings up a customer's three-month supply of the heart medicine digoxin. The total is $113.12— almost 10 times the cost for the same prescription in August.
>
> * * *
>
> "This is starting to create hardship," he says. Many of his customers fall into what is known as the Medicare "doughnut hole," a coverage gap in which patients pay 47.5 percent of branded-drug costs and 79 percent of a generic's price. Russ Clifford, a retired music teacher, learned digoxin's cost had jumped more than fourfold when he picked up his 30-day supply in mid-November. Clifford and his wife have had to dip into savings to pay their rising pharmaceutical bills.[10]

D. Government Investigation

55. The defendants' conduct in generic drug pricing is under investigation by the federal government, including the U.S. Senate and DOJ, as well as a state government investigation.

56. Taro Ltd.'s SEC Form 6-K, filed on September 9, 2016, announced that Taro Inc., "as well as two senior officers in its commercial team, received grand jury subpoenas from the United States Department of Justice, antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with

[9] *See* http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-aslowdown-coming/.

[10] *See* http://www.bloomberg.com/bw/articles/2013-12-12/generic-drug-prices-spike-inpharmaceutical-market-surprise.

competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters."

57. Given the numerous approvals that must occur beforehand, when the DOJ issues grand jury subpoenas, there is a good likelihood that serious antitrust violations have occured. The DOJ's *Antitrust Division Manual* provides that "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution."[11] And if a grand jury request memorandum is approved by the DOJ field office chief, "a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division]."[12] Then, "[t]he DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation."[13] Finally, "[t]he investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."[14]

58. The steep climb of generic drug prices of late is an issue of national importance. In addition to the DOJ subpoenas, Congress has taken a keen interest in the matter. For instance, in October 2014, Senator Bernie Sanders (I-VT) and Representative Elijah E. Cummings (D-MD) launched an investigation into the inexplicably soaring generic drug prices.

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[11] *See Antitrust Division Manual*, Chapter III, Section F.1 at III-82 (2015).

[12] *Id.*

[13] *Id.* at III-83.

[14] *Id.*

59. Sanders and Cummings issued a joint press release at the start of the investigation indicating that had issued letters to 14 pharmaceutical companies, advising "[w]e are conducting an investigation into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life-threatening illnesses." The bicameral duo noted the "huge upswings in generic drug prices that are hurting patients'" and having a "'very significant'" impact threatening pharmacists' ability to remain in business. The legislators made this issue a priority because, for some of their constituents, "the outrageous price hikes are preventing patients from getting the drugs they need.'"[15]

60. The U.S. Senate HELP Committee conducted a hearing on November 20, 2014, "Why Are Some Generic Drugs Skyrocketing in Price?"[16] The committee heard testimony from pharmacist, who explained "it was extremely concerning when about a year ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic drugs."[17] Using generic digoxin and doxycycline as examples of two of the generic drugs with price spikes, the pharmacist explained:

> A recent example from my own experience is the price of Digoxin-a drug used to treat heart failure. The price of this medication jumped from about $15 for 90 days' supply, to about $120 for 90 days' supply. That's an increase of 800%. One of my patients had to pay for this drug when he was in the Medicare Part D coverage gap in 2014. Last year, when in the coverage gap he paid the old price. This year he paid the new price. Needless to say, the patient was astounded, and thought I was overcharging him. The patient called all around to try to get the medicine at the old, lower price, but to no avail. This caused him lots of stress and time, and caused

[15] Press Release, *Congress Investigating Why Generic Drug Prices Are Skyrocketing* (Oct. 2, 2014), http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

[16] http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes.

[17] http://www.help.senate.gov/imo/media/doc/Frankil.pdf.

> us lots of stress and time in explaining the situation, reversing, and rebilling the claim. This example is typical of how these price spikes put consumers and pharmacists in a bad position, often grasping at straws for explanations. And all the while, everyone pays more, including the patient, the pharmacy, and the insurer (often the federal government).[18]

61. Additional congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate, Special Committee on Aging's December 9, 2015 hearing, the Director of the Drug Information Service of the University of Utah noted the deleterious effect these drug prices have had on patient access and healthcare: "[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage."

62. Following the DOJ opening its criminal investigation into generic companies' price hikes on or about November 3, 2014, grand jury subpoenas have been issued to at least 14 generic drug companies, including the defendant Taro Inc.

63. On February 24, 2015, Senator Sanders and Congressman Cummings sent a letter requesting that the Office of the Inspector General ("OIG") of the Department of Health and Human Services "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs."[19] The OIG responded to the request on April 13, 2015 advising would examine pricing for the top 200 generic drugs to "determine the extent to which the quarterly [Average Manufacturer Pricing] exceeded the specified inflation factor."[20]

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[18] *Id.*

[19] http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

[20] http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

64. According to a November 3, 2016, *Bloomberg* report: "U.S. prosecutors are bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion" and that, according to the DOJ, "the first charges could emerge by the end of the year." As predicted, on December 12, 2016, the DOJ charged two generic industry executives with criminal counts related to price collusion for generic doxycycline hyclate and glyburide.

65. The DOJ investigation of the defendants' alleged price-fixing conduct in the generic drug industry is ongoing.

VII. THE GENERIC DRUG MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

66. Because the defendants' anticompetitive conduct constitutes a conspiracy to fix prices, which is a *per se* violation of Section 1 of the Sherman Antitrust Act, the plaintiff does not need to define a relevant market.

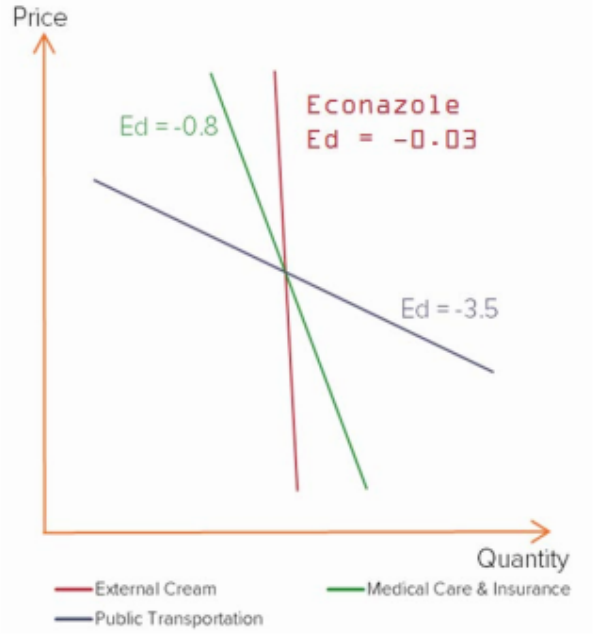
67. The factors necessary to show that a market is susceptible to collusion are present in this case:

(1) *High Level of Industry Concentration* – A small number of competitors, *i.e.* defendants, control a significant market share for generic econazole, as detailed above.

(2) *High Barriers to Entry* – The high costs of manufacture, intellectual property, and expenses related to regulatory approval and oversight are among the barriers to entry in the generic drug market. In addition, the defendants dominate the econazole market, one also considered too small on a worldwide basis to entice most of the world's major drug companies. These barriers to entry and others increase the market's susceptibility to a coordinated effort among the dominant entities in the generic drug industry to maintain supracompetitive prices.

(3) *High Inelasticity of Demand* – For the over-a-million patients regularly prescribed generic econazole, it is a necessity that must be purchased regardless of price hikes. This makes demand for econazole highly inelastic. In fact,

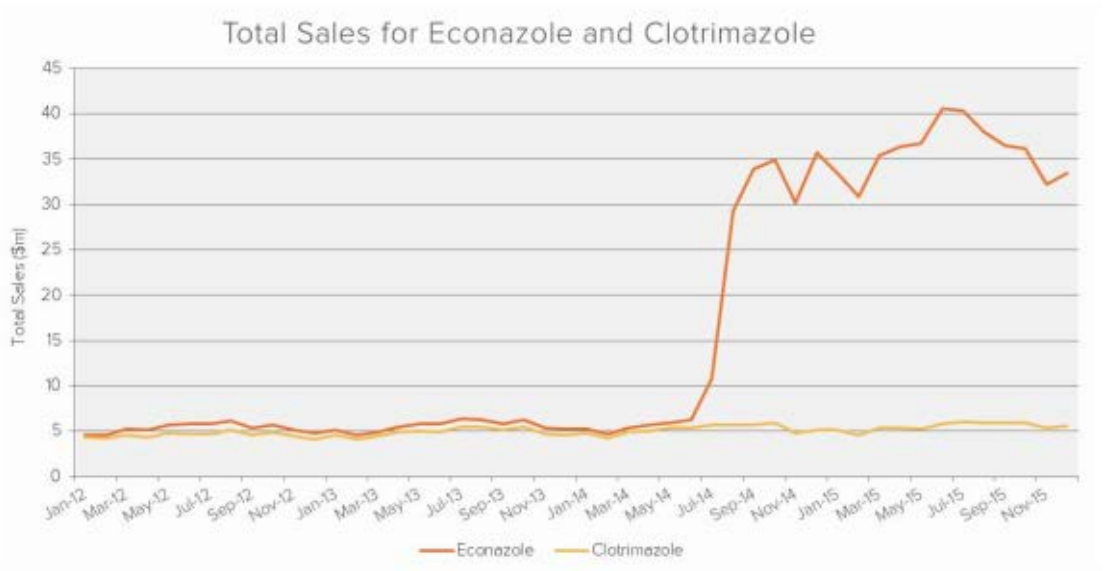
econazole's demand curve is almost perfectly inelastic. As shown in the graph below, a 539% increase in price for econazole leads to only a 17% decrease in quantity demanded. Compare this with medical care and insurance, though, where a 125% price increase would result in no more quantity being demanded. The defendants can exhibit cartel behavior due to this highly inelastic demand. The defendants can significantly raise econazole prices with minimal effect on quantity demanded, and still receive a massive upside of a significant increase in revenue:



Examples	Ed	% Change in Price	% Change in Qd	Elasticity
Econazole	-0.01	539%	-17%	Highly inelastic
Medical Care and Insurance	-0.80	125%	-100%	Relatively inelastic
Public Transportation	-3.50	29%	-100%	Highly elastic

(4) *Lack of Substitutes* – While there are other topical drugs on the market, there are significant barriers to change treatments. Even with a large increase in price for econazole, very few users switched to another drug. For example, compare total sales for econazole to clotrimazole, another drug in the same class as econazole. The graph below shows sales for the two drugs between January 2012

and late 2015 and indicates that, despite the price hike, clotrimazole's sales remained steady. This lack of increase to clotrimazole's sales indicates that very few patients switched to another drug even in the face of a significant price spike:



(5) *Commoditized Market* – The defendants' generic econazole products are fully interchangeable, because they are bioequivalent to one another by FDA standards. Thus, all manufactured version of econazole are therapeutically equivalent to each other and pharmacists may substitute one for another interchangeably.

(6) *Absence of Competitive Sellers* – The defendants have maintained supracompetitive pricing for generic econazole throughout the Class Period. Thus, the defendants have oligopolistic market power in the generic econazole market, which enables the defendants to increase prices without losing market share to non-conspirators. No competitors not part of the conspiracy have emerged to undercut the defendants' supracompetitive pricing.

(7) *Opportunities for Contact and Communication Among Competitors* – The defendants participate in the committees and events of the GPhA, which provides and promotes opportunities to communicate. The grand jury subpoena to Taro Inc., targeting inter-defendant communications, further supports the existence of communication lines between competitors with respect to, among other things, generic econazole pricing.

68. Though it is not necessary to allege a relevant market, at all relevant times, the defendants had substantial market power (*i.e.*, monopoly power) with respect to generic econazole nitrate topical cream because they had the power to maintain the price of the drug at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

69. A small but significant, non-transitory price increase above the competitive level for econazole by the defendants would not have caused a loss of sales sufficient to make the price increase unprofitable.

70. Generic econazole does not exhibit significant, cross-price elasticity of demand with respect to price with any product other than other AB-rated generic versions of econazole.

71. The existence of other medications for the treatment of severe inflammatory skin infections did not constrain the defendants' ability to raise or maintain the price of econazole without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market with econazole. Therapeutic alternatives are not the same as economic alternatives.

72. Because of its labeling, econazole is differentiated from all products other than brand and AB-rated generic versions of econazole.

73. The defendants sold econazole at prices well in excess of marginal costs, and in excess of competitive price, and enjoyed high profit margins.

74. The defendants have had, and exercised, the power to exclude and restrict competition to econazole.

75. The defendants, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to regulatory protections and high costs of entry and expansion.

76. To the extent that the plaintiff is legally required to prove substantial market power circumstantially by first defining a relevant product market, the plaintiff alleges that the relevant market is generic econazole nitrate topical cream or narrower markets contained therein. During the relevant time, the defendants were able to profitably maintain the price of econazole nitrate topical cream substantially above competitive levels.

77. The relevant geographic market is the United States and its territories.

78. At all relevant times, the defendants' market share of the relevant market exceeded 97%, implying a substantial amount of market power.

79. Through their market dominance, the defendants have been able to substantially foreclose the market to rival competition, thereby maintaining and enhancing market power and enabling the defendants to charge the plaintiff and the proposed Class Members inflated prices above competitive levels for generic econazole through unlawful price collusion.

VIII. CLASS ACTION ALLEGATIONS

80. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), the plaintiff brings this action on behalf of a Class defined as:

> All persons or entities that directly purchased generic econazole from one or more of the defendants in the United States and its territories and possessions at any time during the period June 1, 2014 through the present (the "Class Period").
>
> Excluded from the Direct Purchaser Class are the defendants and their officers, directors, management, employees, subsidiaries, or affiliates, judicial officers and their personnel, and all governmental entities

81. Members of the Class are so numerous that joinder is impracticable. The plaintiff believes that there are dozens of Class Members, geographically dispersed throughout the United States such that joinder of all Class Members is impracticable. Further, the Class is readily identifiable from information and records maintained by the defendants.

82. The plaintiff's claims are typical of, and not antagonistic to, the claims of the other Class Members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. The plaintiff and all members of the Class were damaged by the same wrongful conduct of the defendants.

83. The plaintiff will fairly and adequately protect and represent the interests of the Class and the plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

84. The plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.

85. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class Members because the defendants have acted on grounds generally applicable to the entire Class. Thus, determining damages with respect to the Class as a whole is appropriate. The common applicability of the relevant facts to claims of the plaintiff and the proposed class is inherent in the defendants' wrongful conduct, because the overcharge injuries incurred by the plaintiff and each member of the proposed class arose from the same collusive conduct alleged herein.

86. The common legal and factual questions do not vary among class members and may be determined without reference to individual circumstances, and include, but are not limited to, the following:

(a) Whether the defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate

competition and thereby increase the prices of generic econazole in the United States;

(b) The duration and extent of the alleged contract, combination, or conspiracy between and among the defendants and their co-conspirators;

(c) Whether the defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;

(d) The effect of the contract, combination, or conspiracy on the prices of generic econazole in the United States during the Class Period;

(e) Whether defendants' conduct caused supracompetitive prices for generic econazole;

(f) Whether, and to what extent, the conduct of defendants and their co-conspirators caused injury to plaintiffs and other members of the Class; and

(g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

87. Treatment as a class action is the superior method for the fair and efficient adjudication of this controversy, as it will permit numerous similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, avoiding unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding as a class action, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

88. The plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IX. ANTITRUST INJURY

89. During the Class Period, the plaintiff and Class Members directly purchased generic econazole from the defendants. Because of the defendants' anticompetitive conduct, plaintiff and Class Members were forced to pay more for generic econazole than they otherwise would have, and thus have suffered substantial overcharge damages at the hands of the defendants. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

90. The defendants' unlawful conduct has successfully eliminated competition in the market, and the plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to the defendants. The full amount of such overcharge damages will be calculated after discovery and upon proof at trial.

91. The defendants, through their unlawful conduct alleged herein, reduced competition in the generic econazole market, increased prices, reduced choice for purchasers, and caused antitrust injury to purchasers in the form of overcharges.

92. Because the defendants' anticompetitive conduct is ongoing, the plaintiff and the Class continue to pay supracompetitive prices for generic econazole through the present.

X. CLAIM FOR RELIEF – VIOLATION OF SECTION 1 OF THE SHERMAN ACT

93. The plaintiff repeats and re-alleges the foregoing as though fully set forth herein.

94. The defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

95. There is no legitimate, non-pretextual, procompetitive business justification for the defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

96. In violation of Section 1 of the Sherman Antitrust Act, the defendants entered agreements with one another concerning the pricing of generic econazole in the United States. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

97. Each of the defendants has committed at least one overt act to further the conspiracy alleged in this complaint.

98. The conspiracy had its intended effect, because the defendants have benefited—and continue to benefit—from their collusion and the elimination of competition, both of which artificially inflated the prices of generic econazole.

99. As a direct and proximate result of the defendants' unlawful conduct, the plaintiff and Class Members have been injured in their business and property in that they have paid more for generic econazole than they otherwise would have paid in the absence of the defendants' unlawful conduct. The full amount of such damages is presently unknown and will be determined after discovery and upon proof at trial, but is believed to be in the scores of millions of dollars classwide.

100. The defendants' unlawful conduct as alleged herein poses a significant and continuing threat of antitrust injury.

DEMAND FOR RELIEF

WHEREFORE, the plaintiff, on behalf of itseld and Class Members, respectfully demands from this Court:

A. Certification as a class action pursuant to Federal Rule of Civil Procedure 23, and appointment of the plaintiff as the class representative and its counsel of record as class counsel;

B. Adjudication that the acts alleged herein constitute unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

C. A judgment against the defendants, jointly and severally, for the damages sustained by the plaintiff and the class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

D. An award to the plaintiff and Class Members of pre-judgment and post-judgment interest at the highest legal rate provided by law from and after the date of service of this complaint;

E. An award to the plaintiff and Class Members of the costs of this suit, including reasonable attorney fees; and

F. An award of any further relief as the Court deems just and proper.

JURY DEMAND

The plaintiff hereby demands a jury trial on all claims so triable.

Dated: December 27, 2016

Respectfully submitted,

/s/ John D. Radice

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